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|--|-------------|----------------------|---------------------|------------------|
| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/582,858   | 08/14/2008  | Leonardo Marchitto   | 291460US0PCT        | 5966             |
| 22850  | 7590        | 01/06/2012           | EXAMINER            |                  |
| OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.<br>1940 DUKE STREET<br>ALEXANDRIA, VA 22314 |             |                      | PARAD, DENNIS J     |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1612                |                  |
|  |             |                      | NOTIFICATION DATE   | DELIVERY MODE    |
|  |             |                      | 01/06/2012          | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com  
oblonpat@oblon.com  
jgardner@oblon.com

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/582,858             | MARCHITTO ET AL.    |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | DENNIS J. PARAD        | 1612                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 5) ☒ Claim(s) 1 and 3-10 is/are pending in the application.
- 5a) Of the above claim(s) 7,8 and 10 is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 1,3-6 and 9 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/31/2011</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

It is noted that the Examiner in charge of this application has changed. Please address all future correspondence to Examiner Dennis Parad in Art Unit 1612.

Applicant's arguments, filed on 10/31/2011, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Status of the Claims***

Cancellation of claim 2 is acknowledged. Claim 1 and claims 3-6 and 9, which incorporate the limitations of base claim 1, have now been amended such that the scope of the claims now requires a pharmaceutical oral dosage to contain 0.2 to 2.5 parts by weight of tromethamine per one part by weight of non-steroid anti-inflammatory drug ("NSAID").

### ***Information Disclosure Statement***

The information disclosure statement filed on 10/31/2011 is acknowledged.

***Claim Rejections - 35 USC § 103***

**Claims 1-6 and 9 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Penkler et al (WO 97/18245) in view of Ream et al (U.S. Patent Application Pub. No. 2003/0003152) for reasons set forth in the Office Action dated 07/29/2011.**

In the reply filed 10/31/2011, Applicant traversed the rejection for the following reasons:

(1) None of the cited documents suggest how to avoid the throat-irritating effect of ibuprofen, naproxen, and flurbiprofen.

(2) None of the cited art disclose or suggest the specific range of 0.2 to 2.5 parts by weight of tromethamine per one part by weight of NSAID nor do they provide a reasonable expectation of the benefits flowing therefrom.

(3) The experimental results drawn from the Table on pages 8-9 allegedly possess evidence of unexpectedly superior properties.

This is not found persuasive.

In response to Applicant's argument that neither Penkler et al nor Ream et al teach or suggest how to avoid the throat-irritating effect of ibuprofen, naproxen, and flurbiprofen, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicant's assertion that none of the cited art teach or suggest the range of 0.2 to 2.5 parts by weight of tromethamine per one part by weight of NSAID is unfounded. Penkler et al specifically teach formulation having a weight ratio ranging from 1:1 to 100:1 parts by weight of tromethamine to naproxen (pages 7, lines 15-22 to page 8, lines 1-10). It would have been *prima facie* obvious to one of ordinary skill in the art to optimize the concentration range to 0.2 to 2.5 parts by weight of tromethamine to naproxen for reasons set forth on pages 7-8 in the Office Action dated 07/29/2011. Moreover, Penkler et al further teach that the weight ratio of hydroxylamines (i.e. tromethamine) to the remaining pharmaceutical components can be modulated to increase the taste making effects of the complex and, thus, to give a more palatable pharmaceutical formulation (Page 12, lines 13-17).

As to Applicant's allegation of unexpected results, Applicant must compare the claimed subject matter with the subject matter of the prior art to be effective to rebut a *prima facie* case of obviousness. Here, the claims require a pharmaceutical composition comprising glycine, tromethamine, and a NSAID wherein the pharmaceutical composition contains from 0.2 to 2.5 parts by weight of tromethamine per one part by weight of NSAID. In order to compare the efficacy of the particular weight range, Applicant needs to provide evidence that demonstrates that the particular weight ratio range is advantageous over the same composition having a different weight ratio. The comparative results of palatability set forth on pages 8-9 of the Specification, however, do not compare tromethamine to NSAID weight ratio ranges with

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compositions having the same active ingredients. Furthermore, some of the compositions that are compared have identical weight ratios.

For example, Solution G, which Applicant indicates corresponds to the elected invention, comprises a NSAID, tromethamine, and glycine (see page 4 of the Specification). Applicant's evidence of alleged unexpected results compares the palatability of Solution G with the palatability results of Solutions A and D. However, Solutions A and D do not comprise of glycine (see pages 3 and 4 of the Specification). Solution A also lacks tromethamine entirely (see page 3 of the Specification). Moreover, Solutions D and G have the same weight ratio of tromethamine to NSAID (1.5:1; see page 4 of the Specification).

Solution H, which Applicant indicates corresponds to the elected invention, also comprises a NSAID, tromethamine, and glycine (see page 4 of the Specification). Applicant's evidence of alleged unexpected results compares the palatability of Solution H with the palatability results of Solutions B and E. However, Solutions B and E also do not comprise of glycine (see pages 3 and 4 of the Specification). Solution B also lacks tromethamine entirely (see page 3 of the Specification). Moreover, Solutions E and H have the same weight ratio of tromethamine to NSAID (2:1; see page 4 of the Specification).

Finally, Solution I, which Applicant indicates corresponds to the elected invention, also comprises a NSAID, tromethamine, and glycine (see page 5 of the Specification). Applicant's evidence of alleged unexpected results compares the palatability of Solution I with the palatability results of Solutions C and F. However, Solutions C and F also do

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not comprise of glycine (see pages 3 and 4 of the Specification). Solution C also lacks tromethamine entirely (see page 3 of the Specification). Moreover, Solutions F and I have the same weight ratio of tromethamine to NSAID (1.82:1; see pages 4 and 5 of the Specification).

Because the evidence provided by the Applicant does not properly compare the claimed subject matter with the subject matter of the prior art, the *prima facie* obviousness rejection is maintained.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS J. PARAD whose telephone number is

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(571)270-3817. The examiner can normally be reached on Monday through Thursday and every other Friday from 8:30 a.m. to 6:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, FREDERICK F. KRASS can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia A Duffy/  
Primary Examiner, Art Unit 1645

DENNIS J PARAD  
Examiner  
Art Unit 1612